

REMARKS

I. Summary of the Examiner's Action

Claims 25, 27-75, 87, and 89-147 are pending in this application.

Claims 25, 27-43, and 95-143 were withdrawn from consideration as being directed to a non-elected invention.

Applicants' July 13, 2004 amendment was objected to for allegedly introducing new matter.

Claims 46-52 and 65-75 were objected to for having the same scope.

Claims 87 and 89-91 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 144-147 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 92-94, and 144-147 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kaster et al. U.S. Patent No. 5,234,447 (hereinafter "Kaster").

Claims 44-75, 87, 89-94, and 144-147 were rejected under 35 U.S.C. § 102(e) as being anticipated by

Goldsteen et al. U.S. Patent Nos. 5,976,178 and 6,206,912 (hereinafter "Goldsteen").

**II. Applicants' Reply to the
Objection to the Specification**

The Examiner objected to the amendment to the specification made in applicants' July 13, 2004 Reply to Office Action, because the Examiner contends that the amendment's language introduces new matter. Applicants respectfully traverse this objection and illustrate the subject matter's original support as follows.

Applicants amended the specification to specify that the "convolutions of the ring may be thought of as twistable resilient segments interconnecting clip segments 436'" (page 2, 07/13/04 Reply). Serpentine-shaped ring 448 is made from serpentine convolutions (page 24, line 33 thru page 25, line 2), and is configured to resiliently (elastically) self-expand (page 27, lines 5-6). Struts like 436' "may be connected (e.g., welded) to a peak of the serpentine structure" such that the serpentine convolutions interconnect struts 436' (page 26, lines 13-14). When the ring is circumferentially enlarged, "the material in the peaks 458 of the convolutions [of ring 448] tends to twist" (page 26, lines 23-25) (emphasis added). Thus, the convolutions of ring 448 are twistable segments.

The Examiner contends that the twisting described in connection with FIG. 30 is a different embodiment, and cannot teach that the same thing occurs in the embodiment of FIGS. 25 and 26. Applicants respectfully disagree with the Examiner's contention. FIGS. 25, 26, and 30 all illustrate ring 448, which is identical and exhibits the same properties in the various embodiments. Differing components among the various embodiments are highlighted by the use of single or double primes (see page 29, lines 27-29 and page 24, lines 25-28).

Therefore, applicants respectfully submit that the July 13, 2004 amendment to the specification has original support, and request that the objection to the specification be withdrawn.

**III. Applicants' Reply to the
Objection to Claims 46-52 and 65-75**

The Examiner objected to claims 46-52 and 65-75 as having the same scope. Claims 46-52 and 65-75 were copied from an application of another. They were added in a Supplemental Amendment And Notification Pursuant To 37 C.F.R. § 1.604(b) Identifying Published Patent Applications From Which Claims Have Been Copied ("Notification"), filed February 26, 2002. In that Notification, applicants noted that language was being omitted from the claims that did not refer to patentably

distinct features. These omissions resulted in the presentation of the groups of identical claims identified by the Examiner. Applicants acknowledge the requirement to cancel all but one of the duplicate claims from each of the groups of identical claims if they are allowed. However, applicants respectfully resubmit that all of the copied claims are fully supported by the original specification and drawings of this application.

IV. Applicants' Reply to the Rejection of Claims 87 and 89-94 Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 87 and 89-91 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner contends that the language "configuration change is effected by expanding the ring" does not have original support. The Examiner's rejection is respectfully traversed.

Independent claim 87 recites a connector with tissue engaging portions and a cylindrical portion in which the tissue engaging portions change configurations from a first state to a second state in response to an expansion of the cylindrical portion.

Applicants' specification describes struts 436', which have two configurations: (i) an initial configuration where the struts are "held in the form of a distally pointed cone" (page 27, lines 5-6),

and (ii) a subsequent configuration where the struts "flar[e] radially outward" (page 27, line 14).

Struts 436' are configured to be forced through tissue such as the wall of a coronary artery before being allowed to "flare radially outward inside the coronary artery, thereby anchoring the distal end of conduit 430' to the artery" (page 27, line 30 thru page 28, line 2).

The struts are connected to peaks of the serpentine ring (page 26, lines 13-15). When the serpentine structure shown in FIG. 29 or 29a (e.g., the cylindrical portion of the connector) is circumferentially enlarged, the peaks to which the struts are connected twist, causing the struts to twist "(e.g., to bias them in favor of radial outward projection and/or to rotate them about their longitudinal axes to properly orient hooks and/or barbs on them)" (page 26, lines 23-32). This twisting of the struts, which occurs during the expansion of the serpentine structure, causes at least part of the transition of the struts from the initial configuration (penetrating the coronary artery wall) to the subsequent configuration (anchoring the end of the conduit in the artery).

Therefore, applicants respectfully submit that the configuration change being effected, at least in part, by the serpentine ring expansion has original support in the specification. Moreover, applicants

respectfully submit that dependent claims 89-91 are supported by the original specification and that the claims' meanings would be readily apparent to one of ordinary skill in the art. However, if the Examiner requires any further clarification, he is hereby respectfully requested to telephone the undersigned agent for immediate clarification. Thus, applicants respectfully request that the rejections of claims 87 and 89-91 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Applicants' Reply to the Rejection of Claims 144-147 Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 144-147 under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner's rejections are respectfully traversed.

The Examiner contends that the claim language is unclear because the amended specification does not give antecedent basis for clip segments that engage two blood vessels as claimed, because the clip segments of FIG. 25 do not engage two blood vessels. Applicants respectfully traverse the Examiner's contention and submit that the necessary antecedent basis is present.

FIG. 7 shows the distal portion of an illustrative assembly for delivering an artificial conduit (e.g., graft 430) between the aorta and a coronary artery (page 17, lines 17-32). FIG. 25 shows an

illustrative alternative embodiment of the assembly shown in FIG. 7 (e.g., for attaching graft 430 to coronary region 24) (page 25, line 14 thru page 26, line 6).

FIG. 12 shows clip segments/resilient struts 436 engaging coronary artery 20 and graft 430. FIG. 25 shows clip segments 436' engaging graft 430' and waiting to engage coronary artery 20 once clip segments 436' are deployed. Thus, forming a fluid tight connection between graft 430' and an opening in the sidewall of coronary artery 20 is exactly what is shown by FIG. 25.

Therefore, applicants respectfully submit that claims 144-147 are not indefinite, and request that the rejection of claims 144-147 under 35 U.S.C. § 112, second paragraph, be withdrawn. Again, applicants respectfully request that the Examiner telephone the undersigned agent before issuing any further clarity or support rejections as it is believed that all claims in their present form are fully supported by the original specification, and therefore any questions will likely be easily resolved in a brief discussion.

**VI. Applicants' Reply to the Rejection of Claims
92-94 and 144-147 Under 35 U.S.C. § 102(b)**

The Examiner rejected claims 92-94 and 144-147 under 35 U.S.C. § 102(b) as being anticipated by Kaster. Specifically, the Examiner contended that "the cylindrical portion(s) as claimed is met by the

connecting unit (46), the twisting joints are the joints in the engaging members (44) adjacent connecting unit (46) that bend to allow the engaging members (44) to twist about the connecting unit" (Office Action, page 5). Further, the Examiner asserts that claims 92-94 "do not require the tips be capable of forming a hole" (Office Action, page 6). The Examiner's rejections are respectfully traversed.

Applicants' invention as defined by independent claims 92 and 144 is directed toward a connector used to form a fluid-tight anastomotic connection between two blood vessels via the sidewall of one of the blood vessels. With respect to independent claim 92, the first configuration of the tissue engaging portions form a "vessel piercing tip," and with respect to independent claim 144, the twistable resilient segments interconnect the clip segments.

Kaster relates to a vascular anastomotic stapling apparatus. Staples 12 are formed of 316 stainless steel and include a plurality of interior (43) wall and exterior (44) wall engaging members operably joined by a connecting unit 46, or band (see column 5, lines 54-61). However, applicants respectfully submit that Kaster does not show each and every feature of applicants' independent claims 92 and 144.

With respect to independent claims 92, Kaster fails to show a first configuration in which tissue engaging portions form a "vessel piercing tip." Kaster states that stapling tool 10 is manipulated to urge staple 12 and blood vessel 51 through a hole 52 in the wall of a second blood vessel (see column 6, lines 57-61). Furthermore, Kaster explains that hole 52 should be an appropriate diameter to accommodate the exterior diameter of vessel 51 (see column 6, lines 62-65). In other words, there is a preformed hole of the appropriate diameter in the target vessel for the Kaster device. This is in stark contrast to the "vessel piercing tip" of applicants' independent claim 92.

"Pierce" is defined by *The American Heritage® Dictionary of the English Language, Fourth Edition* as "to make a hole or opening in; perforate." See, for example, applicants' FIG. 35, which illustrates a "cone of struts 436'" that "is forced through the wall of coronary artery 20" (page 37, lines 11-12). Thus, it would be apparent to one of skill in the art that applicants' claimed "vessel piercing tip" is a tip that makes a hole in, opens, or perforates a vessel. Applicants respectfully submit that using a previously formed hole would not fully meet the claim language. Kaster does not show a first configuration in which the tissue engaging portions make a hole in, open, or perforate a vessel.

Applicants have not read any additional limitations into the claims and respectfully submit that Kaster fails to show applicants' claimed "vessel piercing tip."

The Examiner did not respond to applicants' remarks in the July 13, 2004 Reply to Office Action in connection with the rejection of claims 144-147 under 35 U.S.C. § 102(b). Applicants therefore request consideration of those arguments, which are recapitulated below for the Examiner's convenience.

Kaster fails to show "a plurality of twistable resilient segments that interconnect the clip segments," (emphasis added), as described by applicants' independent claim 144. The Examiner contends that the engaging members of Kaster twist about the connecting unit. However, Kaster fails to show twistable segments interconnecting the engaging members. The engaging members of Kaster, which are described as being flexible in a radial direction, are interconnected by a stainless steel ring, which is not described to have any resilient or twistable properties. If anything, the stainless steel ring appears to be rigid and of a fixed size and shape. In stark contrast, applicants' FIG. 25 illustrates resilient serpentine ring 448 that may be formed to hold struts 436' substantially uniformly out against the inner surface of body tubing all the way around the circumference of the graft (see page 25,

lines 10-13). Twistable resilient segments actually interconnect the clip segments in applicants' independent claim 144. This feature is not shown by Kaster.

Because Kaster fails to show, expressly or inherently, each and every feature of applicants claimed invention as defined by independent claims 92 and 144, the rejection of independent claims 92 and 144 should be withdrawn. Furthermore, since claims 93-94 and 145-147 depend from independent claims 92 and 144, the rejection of claims 93-94 and 145-147 should also be withdrawn. Therefore, applicants respectfully request that the rejection of claims 92-94 and 144-147 be withdrawn.

VII. Applicants' Reply to the Rejection of Claims 44-75, 87, 89-94, and 144-147 Under 35 U.S.C. § 102(e)

The Examiner rejected claims 44-75, 87, 89-94, and 144-147 under 35 U.S.C. § 102(e) as being anticipated by Goldsteen. This rejection is respectfully traversed.

35 U.S.C. § 102(e) states "[a] person shall be entitled to a patent unless the invention was described in ... (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent" (emphasis added). MPEP § 2136.04 states that "another" means a different inventive entity and that the "inventive entity is different if not all inventors are the same."

The Examiner contends that the Goldsteen patents have an additional inventor, Rudy Mazzocchi. Applicants respectfully submit that the record reflects common inventorship among the Goldsteen patents and the present application. Applicants refer the Examiner to a Request to Correct Inventorship Under 37 C.F.R. § 1.48(c), filed April 22, 2002, which was made to include Rudy Mazzocchi as an inventor in the present patent application (copy attached hereto as Appendix A). Applicants also refer the Examiner to the February 6, 2003 Office Action in which the Examiner acknowledges the Request to Correct Inventorship and informs applicants that Rudy Mazzocchi has been added as an inventor (copy attached hereto as Appendix B). Applicants therefore respectfully submit that the inventive entity of the present application and the Goldsteen patents is the same, and submit that the Goldsteen patents are not prior art for purposes of 35 U.S.C. § 102(e).

Therefore, applicants respectfully request that the rejection of claims 44-75, 87, 89-94, and 144-147 under 35 U.S.C. § 102(e) be withdrawn.

VIII. Contingent Request for Telephonic Interview

If for any reason the Examiner is unable to allow claims 44-75, 87, 89-94 and 144-147 of the present application based on this Reply, applicants respectfully

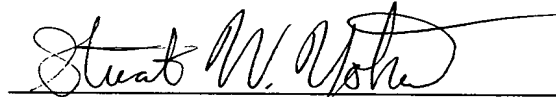
request a telephonic interview with the Examiner before the issuance of an Advisory Action.

IX. Conclusion

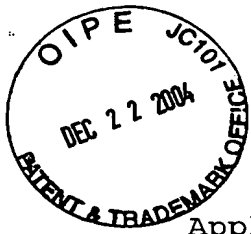
For at least the foregoing reasons, applicants respectfully submit that claims 44-75, 87, 89-94, and 144-147 are allowable. Therefore, this application is in condition for allowance.

Accordingly, prompt reconsideration and allowance of this application are respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Stuart W. Yother", is written over a horizontal line.

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APPENDIX A

293/008 Cont.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas J. Bachinski et al.
Application No.: 09/406,575 Confirmation No.: 1763
Filed : September 24, 1999
For : MEDICAL GRAFTING CONNECTORS AND
FASTENERS
Group Art Unit : 3738
Examiner : Paul Prebilic

New York, New York 10020
April 22, 2002

Commissioner for Patents
P.O. Box 2327
Arlington, Virginia 22202

REQUEST TO CORRECT INVENTORSHIP
UNDER 37 C.F.R. § 1.48(c)

Sir:

Pursuant to 37 C.F.R. § 1.48(c), applicants hereby request to amend the above-identified patent application to correct the inventorship by adding Rudy Mazzocchi as an inventor of the subject matter claimed in this application.

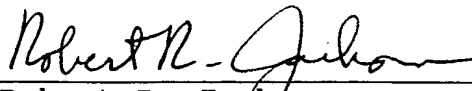
In support of this Request, applicants file herewith the following:

1. A Statement executed by Rudy Mazzocchi, stating that the error by which he was not named an inventor occurred without deceptive intent;
2. A new Declaration And Power Of Attorney naming the inventors, Thomas J. Bachinski, David S. Goldsteen, Daniel J. Sullivan, and Rudy Mazzocchi; and
3. The Consent Of Assignee To Change In Inventorship Pursuant To 37 C.F.R. §§ 1.48(c) And 3.73(b).

Pursuant to 37 C.F.R. § 1.17(i), applicants have enclosed a check in the amount of \$130.00 to pay the

required fee. The Director is hereby authorized to charge payment of any additional fee required in connection with this Request, or to credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this Request is enclosed.

Respectfully submitted,



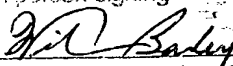
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I hereby certify that this correspondence is being communicated with the U.S. Patent Service via First Class Mail in an envelope addressed to:
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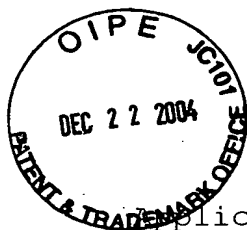
4/22/02

William Bailey

Name of person signing



Signature of person signing



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Examiner : Paul Prebilic

Commissioner for Patents
Washington, D.C. 20231

STATEMENT OF RUDY MAZZOCCHI
PURSUANT TO 37 C.F.R. § 1.48(c)(2)

Sir:


I, Rudy Mazzocchi, declare that

1. My addition as an inventor was necessitated by a Supplemental Amendment filed on February 26, 2002, adding new claims to the above-identified patent application.

2. The inventorship error occurred without deceptive intention on my part.

3. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of any patent issuing on this application.

Date: 4/11/02


Rudy Mazzocchi